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5. 510(k) Summary

Additional Information to Premarket Notification Summary

JUN 11 2010

1. Sponsor Information:
   Laboratories URGO
   42 Rue de Longvic
   21300 Chenove
   France

   Contact Person: Sophie Fortin
   Regulatory Affairs Director
   Phone: +33.(0)3.80.44.28.78
   Fax: +33.(0)3.80.44.71.40
   Email: s.fortin@fr.urgo.com

2. Device Name:
   Common or Usual Name: Antimicrobial Wound Dressing with Silver
   Proprietary Name: Urgotul Ag
   Classification Name: Unclassified

3. Predicate Devices:
   Urgotul Ag (K061220), Laboratoires URGO
   Urgocell Ag (K062559), Laboratoires URGO

4. Description of Device
   Urgotul® Ag, antimicrobial wound dressing with silver, is a non-adhesive, non-occlusive, antimicrobial hydrocolloid wound contact dressing, composed of a polyester mesh impregnated with a matrix comprising of hydrocolloid particles (carboxymethylcellulose), cohesion polymers, petroleum jelly and silver (2.25 mg/sq.inch).

5. Indications for Use
   The barrier functions of Urgotul® Ag, antimicrobial wound dressing with silver, may help reduce infection in light to moderate exudative partial and full thickness wounds, including diabetic ulcers, first and second degree burns, decubitus ulcers, venous stasis ulcers, and graft and donor sites.

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6. Technological Characteristics

FUNCTION	Urgotul Ag (K062559)	Urgotul Ag
Indications for Use	The barrier functions of Urgotul® Ag, antimicrobial wound dressing with silver, may help reduce infection in light to moderate exudative partial and full thickness wounds, including diabetic ulcers, first and second degree burns, decubitus ulcers, venous stasis ulcers, and graft and donor sites.	The barrier functions of Urgotul® Ag, antimicrobial wound dressing with silver, may help reduce infection in light to moderate exudative partial and full thickness wounds, including diabetic ulcers, first and second degree burns, decubitus ulcers, venous stasis ulcers, and graft and donor sites.
Structure	Composed of a non-adhesive, non-occlusive, antimicrobial hydrocolloid wound contact dressing, composed of a polyester mesh impregnated with a matrix comprising of hydrocolloid particles (carboxymethylcellulose), cohesion polymers, petroleum jelly and silver (2.25 mg/sq.inch).	Composed of a non-adhesive, non-occlusive, antimicrobial hydrocolloid wound contact dressing, composed of a polyester mesh impregnated with a matrix comprising of hydrocolloid particles (carboxymethylcellulose), cohesion polymers, petroleum jelly and silver (2.25 mg/sq.inch).
Antimicrobial activity	Studies of antimicrobial activity against MRSA, Pseudomonus aeruginosa, and Streptococcus pyogenes	Studies of antimicrobial activity against MRSA, Pseudomonus aeruginosa, Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, and Candida albicans

7. Description of Safety and Substantial Equivalence:

Safety Studies

The standard battery of safety and biocompatibility studies that were previously conducted showed the Urgocell Ag to be comparable to predicate devices and other silver containing wound dressings. These studies included: Cytotoxicity, Irritation study in rabbit, and Sensitization study in guinea pigs.

Studies of the antimicrobial activity of Urgotul Ag wound dressing (K061220) were previously conducted against MRSA, Pseudomonas aeruginosa, and Streptococcus pyogenes. With this submission, data was submitted concerning the antimicrobial activity of Urgocell® Ag on three new strains: *Enterococcus faecalis, Escherichia coli* and *Candida albicans.*

Substantial Equivalence

Urgotul Ag compared to Urgotul Ag (K061220) shows substantial equivalence in comparable functions and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 11 2010

Laboratories URGO
% Ms. Sophie Fortin
Regulatory Affairs Director
42 Rue de Longvic
21300 Chenove, France

Re: K100430
Trade/Device Name: Urgotul Ag Antimicrobial Wound Dressing with Silver
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 25, 2010
Received: June 03, 2010

Dear Ms. Fortin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Statement of Indications for Use

510(k) Number (if known): K100430

Device Name: URGOTUL AG, Antimicrobial Wound Dressing with Silver

Indications For Use:

The barrier functions of Urgotul Ag, antimicrobial wound dressing with silver, may help reduce infection in light to moderately exudative partial and full thickness wounds, including diabetic ulcers, first and second degree burns, decubitus ulcers, venous stasis ulcers, and graft and donor sites.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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